

# Identification and naming of substances under REACH and CLP

The document aims to explain in simple terms the main principles behind the identification and naming of substances

Version 2.0  
April 2017



## **LEGAL NOTICE**

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

<b>Reference:</b>	ECHA-17-G-08-EN
<b>Cat.Number:</b>	ED-02-17-228-EN-N
<b>ISBN:</b>	978-92-9495-792-4
<b>DOI:</b>	10.2823/46787
<b>Publ.date:</b>	April 2017
<b>Language:</b>	EN

The European Chemicals Agency (ECHA) is producing a series of “simplified” versions of the REACH (CLP) guidance documents in order to make the corresponding REACH (CLP) guidance documents published by the Agency more accessible for industry. As short summaries, these documents cannot contain all details included in the full guidance documents. Thus, in case of doubt, it is recommended to consult the full guidance documents for further information.

© European Chemicals Agency, 2017

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers to) using the Guidance feedback form. The Guidance feedback form can be accessed via the “Support” section of the ECHA website at: [comments.echa.europa.eu/comments/cms/FeedbackGuidance.aspx](https://comments.echa.europa.eu/comments/cms/FeedbackGuidance.aspx).

## **European Chemicals Agency**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland  
Visiting address: Annankatu 18, Helsinki, Finland

## Table of Contents

<b>1. INTRODUCTION</b> .....	<b>4</b>
<b>2. ESSENTIAL TO UNDERSTAND</b> .....	<b>4</b>
2.1 Why it is important to clearly identify a substance .....	4
2.2 Definition of “substance” in REACH and CLP .....	5
<b>3. WHAT ARE THE TYPES OF SUBSTANCES UNDER REACH AND CLP?</b> .....	<b>5</b>
3.1 Well-defined substances .....	5
3.2 UVCB .....	6
<b>4. HOW TO IDENTIFY AND NAME A SUBSTANCE?</b> .....	<b>7</b>
4.1 Requirement for substance identification in REACH .....	7
4.2 Substance naming .....	7
<b>5. ADVICES FOR ESTABLISHING IF SUBSTANCES ARE THE SAME</b> .....	<b>8</b>
<b>6. INQUIRY</b> .....	<b>8</b>
<b>7. REFERENCES AND FURTHER INFORMATION</b> .....	<b>8</b>

## 1. Introduction

This Guidance in a Nutshell gives a simple and concise introduction on how to identify and name a substance under Regulations (EC) No 1907/2006 (REACH Regulation) and (EC) No 1272/2008 (CLP Regulation). Furthermore, it provides the basic principles to establish whether substances can be regarded as the same in the context of these regulations.

This Guidance in a Nutshell is aimed at managers and decision-makers of companies producing or importing chemical substances in the European Economic Area (EEA)<sup>1</sup>, particularly those belonging to the Small and Medium Enterprises (SME) category. Reading this document will allow them to define the main elements necessary to identify and name substances and establish sameness for REACH and CLP purposes and to decide whether they need to read the full *Guidance for identification and naming of substances under REACH and CLP*<sup>2</sup> (“parent guidance”).

## 2. Essential to understand

### 2.1 Why it is important to clearly identify a substance

The REACH Regulation focuses on substances. Although the provisions of the Regulation apply to the manufacturing, placing on the market or use of substances on their own, in mixtures or in articles, the registration requirements apply only to substances.

Unambiguous and clear substance identification is an essential preliminary step in order to comply with the requirements for substances falling within the scope of the REACH and CLP Regulations and to establish whether they fulfil the requirements for exemptions from certain provisions of these Regulations. To identify a substance each company needs to use specific identification parameters defined in Annex VI of the REACH Regulation which will be required for the different REACH and CLP processes. These will be necessary not only for companies but also for authorities in order to carry out their duties. The approach to identify a substance depends on the substance type, as described in section 3 of this document.

REACH requires that registrants of the same substance have to be part of the same “joint submission” and submit certain information together. Registrants of the same substance have to comply with important data-sharing obligations<sup>3</sup>.

Furthermore, the authorities will need to rely on correct substance identification when they have to carry out a substance evaluation and manage restrictions and authorisation.

Industry also needs to identify substances for the purposes of the CLP Regulation, and the same approach as is outlined in this guidance document for the purposes of REACH applies. For notification to the Classification and Labelling inventory under CLP applicants have to submit some of the same identification information as is required by REACH.

---

<sup>1</sup> The European Economic Area is composed of Iceland, Liechtenstein, Norway and the 28 European Union Member States.

<sup>2</sup> The full Guidance for identification and naming of substances under REACH and CLP, together with all other ECHA Guidance documents, is available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

<sup>3</sup> Detailed information about data-sharing obligations and joint submission of data is provided in the *Guidance on data-sharing* available in the support section of the ECHA website (see footnote 2).

## 2.2 Definition of “substance” in REACH and CLP

A substance is defined in REACH by Article 3 and in CLP by Article 2 as:

*“a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”.*

The definition is the same as the one used under the previous legislation<sup>4</sup> and goes beyond a pure chemical compound composed of a single molecule. The term covers both substances **obtained by a manufacturing process** and substances in their **natural state** and which can both include several constituents within the substance which have to be taken into account as far as possible when identifying the substance for REACH and CLP purposes.

For REACH and CLP purposes a substance may contain:

- one or more **main constituents**: constituent(s) that make(s) up a significant part of that substance and are therefore used in substance naming and identification; the main constituent(s) should clearly be other than the following two.
- **impurities**: all the unintentional constituents coming from the manufacturing process or from the starting material(s). These could be the result of secondary or incomplete reactions occurring during the production and are present in the final substance even if not sought by the manufacturer.
- **additives**: all the constituents which are intentionally added to stabilise the substance and only for this purpose.

The reader has to carefully consider the difference between a substance and a **mixture**. A mixture consists of several different substances. Each individual component substance in a mixture needs to be identified, and when required registered according to REACH and/or notified according to CLP either by the substance manufacturer or by the importer of the mixture.

## 3. What are the types of substances under REACH and CLP?

When identifying substances under REACH and CLP the basic rule to be followed is that a substance should be defined as far as possible by its chemical composition (the content of each constituent, the main impurities and any additives) and its chemical identity (name, numerical identifiers, molecular information).

Substances can be divided into two main groups:

### 3.1 Well-defined substances

When the composition of the substance can be quantitatively and qualitatively defined and the registrant is able to provide a chemical specification of the constituents, the substance will be considered as a **“well defined substance”**. The registrant will be able to identify all the constituents, covering the composition up to 100%. To decide whether it should be considered as **mono-constituent** or instead as **multi-constituent** the so-called **“80%- 20%”** and **“80%-10%” rules** are applied.

---

<sup>4</sup> 7<sup>th</sup> amendment of the Dangerous Substance Directive (Directive 92/32/EEC amending Directive 67/548/EEC).

If **one constituent** is present at a concentration of **at least 80% (w/w)** and **the impurities** make up **no more than 20% (w/w)**, the substance will be considered as mono-constituent. As noted above intentionally added substances other than those added to stabilise the substance are separate substances that are not to be considered in the main mass balance.

If **more than one main constituent** is present in a concentration **between 10% and 80% (w/w)** the substance is considered as a multi-constituent substance.

Since it will not always be possible to strictly apply this rule, deviations may be accepted when appropriate and justified. Reasoning based on physico-chemical characteristics or the hazard profile might justify a substance being considered as mono-constituent, even if the main constituent is below 80% or its range of concentration overlaps the 80% criterion.

Furthermore, some substances whose composition is fully known may need additional identifiers in order to be unequivocally identified, e.g. crystalline structure, IR absorption peaks or physical or chemical properties. These substances will be named following the same convention as for mono- or multi-constituent substances, but the necessary identification parameters should be provided.

Further information on identification and naming of well-identified substances is given section 4.2 of the parent Guidance.

### 3.2 UVCB

There are substances for which the number of constituents is high, or the composition is to a significant extent unknown, or the variability of composition is large or unpredictable. In these cases a clear identification based on the chemical composition only is not possible and these will need to be considered as a substances of **Unknown** or **Variable** composition, **Complex** reaction products or **Biological** materials (UVCB).

Various types of substances can be grouped under the UVCB umbrella. Typically they should be identified by considering the **origin material** of the substance, the most relevant steps during the **manufacturing process** and, according to the specific case, other relevant parameters (in addition to what is known about their chemical composition).

Four main sub-types of UVCB have been defined:

*UVCB sub-type 1* where the source is biological and the process is synthesis. The biological material is modified by means of a (bio)chemical process resulting in new constituents;

*UVCB sub-type 2* where the source is chemical or mineral and new molecules are synthesized by means of (bio)chemical reactions;

*UVCB sub-type 3* where the source is biological and the process is a refinement, and new molecules are intentionally generated;

*UVCB sub-type 4* where the source is chemical or mineral and the process is a refinement, without intentional chemical reactions.

It is recognised that there will be borderline cases between well-defined and UVCB substances; e.g. substances which are produced by means of reactions between many constituents, each within a broad range, or reaction products with variable and poorly predictable composition. When encountering such unclear cases, the reader is advised to refer to the parent *Guidance for identification and naming of substances under REACH and CLP*.

Further information on identification and naming of UVCB substances is given section 4.3 of the parent Guidance. Specific guidance on certain substance types is also available as indicated in section 7 of this document.

## 4. How to identify and name a substance?

### 4.1 Requirement for substance identification in REACH

The full identification of a substance under REACH requires the following information:

- **chemical composition** of the substance, considering, where appropriate, impurities and additives besides main constituent(s) and respective typical concentrations and concentration ranges;
- **chemical identity** of the constituent(s) by means of IUPAC name plus other identifiers when available, e.g. EC number, CAS number. For UVCB substances information on the source and manufacturing process is also necessary;
- **molecular and structural information**; this must be defined, when available and appropriate, by molecular and structural formula, information on optical activity, ratio of isomers, molecular weight or molecular weight range;
- **Spectral and analytical data** sufficient to confirm the structure and the composition of the substance.

The data to enable a substance to be identified are listed in section 2 of REACH *Annex VI*. As a general rule, all this information is required regardless of the substance type. However, if it is not technically possible or not scientifically necessary to give a particular piece of information, a reasoned justification should be given to enable the scientific validity to be assessed.

Known constituents which are relevant for the classification of a substance have always to be fully identified for both REACH and CLP purposes.

### 4.2 Substance naming

The rules to be followed for a correct naming under REACH are related to the substance type as explained in sub-chapters 3.1 and 3.2. For well-defined substances and UVCB substances different approaches and parameters should be considered.

**Well-defined mono-constituent substances** are named after the main constituent, using its IUPAC name. Other internationally recognized designations may be given as additional information.

**Well-defined multi-constituent substances** are named as a reaction mass of the main constituents of the substance. The generic format to be used is "Reaction mass of [names of main constituents]", with the list of constituents presented in alphabetical order and separated by the conjunction "and".

**UVCB substances** are named by combining, in this order, source and process. Depending on whether the source is biological or non-biological, the name of the species (genus, species, family) or the starting material (IUPAC name) are to be used. The process must be identified by the chemical reaction, in the case of synthesis of new molecules, or the type of refinement step. In some cases, e.g. for combined processing, more than one single step will need to be specified in addition to the information on the source. There are also borderline cases where

UVCB substances could be named based on the constituents. The parent Guidance (section 4.3.2) provides support on a few specific groups of UVCB substances.

Section 7 of the parent Guidance provides further examples on how the user could work with the principles outlined in the document.

## **5. Advices for establishing if substances are the same**

Under REACH, registrants of substances having the same EC identifier have to be part of the same "joint submission" and submit certain information together. Different manufacturers/importers having substances with the same EC identifier always need, nevertheless, to verify that the rules set out in the parent Guidance for identifying and naming their substances confirm that they have the same substance and that they can share the hazard data relevant for that substance.

For well-defined substances, the rules described in section 3.1 of this document, for mono-constituent substances and for multi-constituent substances are applied.

The consequence of defining a substance as UVCB is that any significant change of source or process would be likely to lead to a different substance (see also section 3.2).

Further information can be found in section 5 of the parent guidance.

## **6. Inquiry**

For non phase-in substances, or phase-in substances that have not been pre-registered, the potential registrants have the duty to inquire from the Agency whether a registration has already been submitted for the same substance as they intend to register. This inquiry must include information on the identity of the potential registrant, the identity of the substance and on which new studies would be required by the potential registrant to comply with the information requirements.

The Agency will then establish whether the same substance has previously been registered and the result will be communicated to the potential registrant. Any previous or other potential registrants will be informed accordingly.

## **7. References and further information**

This Guidance in a Nutshell provides a summary of key elements necessary to correctly identify and name a substance. However, it is recommended that before a registration under REACH or notification under CLP is made, particularly in complex cases, manufacturers and importers should consult the full parent *Guidance for identification and naming of substances under REACH and CLP* in order to ensure that they correctly define the main elements necessary to identify and name the substance concerned.

The parent guidance document provides more detailed examples and explanations of the concepts introduced by the present document. Additional insight may also be gained particularly by consulting the following web pages:



- 
- the ECHA Dissemination portal which is a unique source of information on the chemicals manufactured in and imported into Europe at <https://echa.europa.eu/information-on-chemicals>;
  - Sector-specific support for substance identification on the ECHA website at <https://www.echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification/oleochemicals>;
  - The IUCLID 5 website at <http://iuclid.echa.europa.eu>;
  - The official IUPAC website at <http://www.iupac.org>;
  - Recommendations on Organic & Biochemical Nomenclature, Symbols & Terminology at <http://www.chem.qmul.ac.uk/iupac>;
  - The official website of the CAS registry service which can be consulted to retrieve CAS numbers at <http://www.cas.org>;
  - The free SMILES (Simplified Molecular Input Line Entry Specification) generator at <https://cactus.nci.nih.gov/translate/>.

EUROPEAN CHEMICALS AGENCY  
ANNANKATU 18, P.O. BOX 400,  
FI-00121 HELSINKI, FINLAND  
ECHA.EUROPA.EU